

AMENDMENTS TO THE SPECIFICATION:

Please insert prior to the paragraph beginning on line 8, page 1 the following heading:

Field of the Invention

Please insert prior to the paragraph beginning on line 11, page 1 the following heading:

Background and Summary

Please replace the paragraph beginning on line 14, page 1 with the following:

[[US]]U.S. Patent No. 3,822,461 discloses a disposable lancet for puncturing human skin in order to obtain a volume of blood. The lancet according to this solution is designed in such a way that a minimum amount of material is used to produce it and, consequently, production costs are kept low. The design of the disposable lancets allows a plurality of lancets to be punched out from one material strip, so as to guarantee economic production. According to the method disclosed in [[US]]U.S. Patent No. 3,822,461, in which individual lancets are obtained with a puncturing portion at one end of a metal strip, and with a shoulder formed there, the respective individual lancet is punched out from a material strip. The width of the material strip corresponds substantially to the length of the lancet. The lancets are punched out alternately from the strip, the tip of one lancet pointing in one direction, and the individual lancet to be punched out next to this one facing in the other direction. In each punching operation, individual lancets are obtained whose outer contour is defined by the punching tool. Each of the lancets punched out comprises an elongate depression which reaches from the handling end to the puncturing end of the lancet and stiffens the latter in such a way as to increase the stiffness and the security against bending of each lancet punched out from the continuous strip, so that the lancet does not buckle during use.

Please replace the paragraph beginning on line 31, page 1 with the following:

Furthermore, DE 197 53 847 A1 ~~has disclosed~~ discloses an analytical test element with a capillary channel. This analytical test element is used to determine an analyte in a liquid and comprises an inert support, a detection element, and a channel suitable for capillary liquid transport. This channel has a sample application opening at one end, and a vent opening at the other end. The channel suitable for capillary liquid transport is at least

partially formed by the support and the detection element. The channel for capillary liquid transport reaches from the sample application opening at least as far as that edge of the detection element lying nearest the vent opening. A recess is situated in a surface forming the channel suitable for capillary liquid transport, at that edge of the test element forming the sample application opening. In this way, that edge of the test element forming the sample application opening is at least partially interrupted on one side, the surface located opposite the recess lying free. At least one of the faces forming the inner surface of the channel suitable for capillary liquid transport is made hydrophilic. This is done either by using a hydrophilic material or by coating a less hydrophilic material with a hydrophilic layer. A layer of oxidized aluminium, for example, is suitable for rendering it hydrophilic.

Please replace the paragraph beginning on line 11, page 2 with the following:

According to the solution known from DE 197 53 847 A1, a two-sided adhesive tape is affixed. This includes a cutout which is a few millimetres in width and several millimetres in length and by means of which the dimension of the capillary channel is defined. A detection film, specifically designed for the detection of glucose for example, is affixed to the adhesive tape. The detection film covers the central, notch-like cutout in the adhesive tape. A cover layer is affixed to the exposed area of the adhesive tape so that the cover layer and detection film lie directly on one another. The cover layer is a laminate of a relatively thick, stable plastic film and a thin hydrophilic AluO_x layer. The hydrophilic layer has to extend into the gap between the cover layer and detection film. When the cover layer is fitted on the adhesive tape, it is necessary to arrange the protruding end of the thinner film, i.e. of the thin hydrophilic AluO_x layer, between the detection element and the thicker film of the cover layer. In such a production method, errors can arise because of the large number of adhesion operations that have to be performed with great precision. Because of the method steps that have to be followed, this method is relatively time-consuming.

Please replace the paragraph beginning on line 26, page 2 with the following:

DE 101 42 232 A1 discloses an analytical aid with a lancet and a test element. The analytical aid includes a lancet having a lancet needle and a lancet body. The lancet needle is displaceable relative to the lancet body, the lancet body being made of an elastic material in the area of the tip of the lancet needle. This material is embedded into the tip of the lancet needle. An analytical test element is connected fixedly to the lancet body. Also disclosed is a lancet-containing analytical aid having a lancet which has a lancet needle and

a lancet body. The lancet body is designed as a hollow body in the area of the tip of the lancet needle. The hollow body surrounds the tip of the lancet needle, said lancet needle being displaceable relative to the lancet body, and the hollow body being made at least partially of an elastic material, and an analytical test element which is connected fixedly to the lancet body.

Please replace the paragraph beginning on line 2, page 3 with the following:

~~In view of the cited disadvantages of the prior art, the object of the invention is to make available~~ An illustrated embodiment of the present invention provides a method by which puncturing and measuring devices ~~can~~ may expediently be connected and ~~can~~ may be produced in a substantially automated production process.

Please delete the following paragraph beginning on line 6, page 3:

~~According to the invention, the object is achieved by the features of Patent Claim 1 and by those of Patent Claim 18.~~

Please replace the paragraph beginning on line 9, page 3 with the following:

In one method step, a recess, preferably of triangular configuration, is produced on the band-shaped support material. In this way, a puncturing point is produced with which the human skin can be punctured. The edges delimiting the recess are ground and sharpened, in particular in the area of their point, so that a point suitable for puncturing the human skin is formed on one long side of the band-shaped support material. The side of the band-shaped support material, for which a thin metal film of 0.1 to 0.3 mm thickness can be used, is surrounded by a plastic material in order to protect against injuries and damage and to ensure sterility of the final product. A soft plastic strip, for example made of silicone, and surrounding the points, is preferably used for this purpose. That side of the band-shaped support material remote from the puncturing points is likewise provided with a strip of plastic material, in order to make handling easier, this strip of plastic material surrounding that side of the band-shaped support material is remote from the puncturing points. This strip, made of any desired plastic material, serves for better handling of the finished combination of lancet and test strip. At this stage in the production process, the band-shaped support material with the embedded lancet points, which are surrounded by soft plastic, for example silicone, can now be sterilized by β or γ irradiation.

Please replace the paragraph beginning on line 34, page 3 with following paragraph:

_____ The detection material is now applied to the band-shaped support material in which the puncturing points are formed and which is surrounded by a strip of silicone material at the side having the puncturing points, while the opposite side is provided with a strip of plastic material. The area between the soft plastic material covering the puncturing points and the plastic strip of the band-shaped support material facilitating handling is covered over with an affixed cover film which borders the detection element. The band-shaped support material is now completely covered over. At the side on which the ground and sharpened puncturing points are formed, the band-shaped support material is surrounded by a silicone strip, to which a cover film is adjoined. The cover film lies on a detection element which has been applied in strip form on the band-shaped support material and which in turn lies on the plastic material facilitating handling of the band-shaped support material. By means of the method proposed according to the invention, it is advantageously possible to ensure that the band-shaped support material, from which individual puncturing/measuring disposable bodies are separated, can be sterilized by β or γ irradiation prior to application of a detection element. ~~Only after~~ After sterilization of the band-shaped support material is completed is the detection element applied, so that the function and mode of action of the detection element is not adversely affected by the sterilization of the band-shaped support material by β or γ irradiation, because it is not exposed to this irradiation, thanks to the fact that it is applied later to the band-shaped support material. The detection element can either be applied directly in the area of the sharpened puncturing points or can also be applied to depressions which have been incorporated in the band-shaped support material and which form a channel for capillary liquid transport. Both variations of the arrangement of the detection element are possible.

Please replace the paragraph beginning on line 1, page 5 with the following:

In a particularly advantageous manner, the puncturing and measuring devices can be produced from a continuous support material into which, according to one method step, depressions with a small width of approximately 0.25 mm have first been incorporated. An important feature of the application of the notches to the band-shaped support material is that the thin metal film preferably used as band-shaped support material, and of only a few tenths of a millimetre thick, is not pierced through, and instead form notches [[form]] which, depending on the notching tool, can have a rounded notch base or a triangular notch base, for example. Other geometries of the base of the depressions are also possible.

Please replace the heading on line 30, page 5 with the following:

~~Drawing~~ Brief Description of the Drawings

Please replace the Brief Descriptions of the Drawings beginning on line 34, page 5 through line 27, page 6 with the following:

Figure 1——_shows the plan view of a band-shaped support material used as raw material,

Figure 2——_shows the plan view of the band-shaped support material with depressions in the form of grooves or notches arranged in a selectable division,

Figure 3——_shows the band-shaped support material with puncturing points punched out on its first face,

Figure 4——_shows the puncturing points, covered by soft plastic strips, and a plastic material located opposite these and serving as a grip,

Figure 5——_shows the application of a cover film and of a detection material between the silicone material and the plastic material on the top face of the band-shaped support material,

Figure 6——_shows the plan view of an individual puncturing/measuring disposable body separated from the band-shaped support material and with covered puncturing point,

Figure 7 ——_shows an individual puncturing/measuring disposable body with exposed puncturing point,

Figure 8 ——_shows a cross section through the area of the individual puncturing/measuring disposable body, covered by the detection field, according to cross section line VIII-VIII, and

Figure 9——_shows a cross section through the individual puncturing/measuring disposable body according to Figure 7, according to cross section line IX-IX, the groove or notch having a triangular base.

Please replace the heading on line 30, page 6 with the following:

Embodiments Detailed Description of the Drawings

Please replace the paragraph on line 26, page 7 through line 10, page 8 with the following:

Figure 3 shows the production of recesses which delimit puncturing points on a first face of the band-shaped support material. If necessary, the height h of the test band can at the same time be shortened in this method step. It will be seen from the view in Figure 3 that recesses 11 are produced on the first face 9 of the band-shaped support material 1. The recesses 11 can, as is shown in Figure 3, be made triangular, for example. The point of the recesses 11 directed away from the first face 9 preferably coincides with the separating line 5 according to the view in Figure 2. The recesses 11 are delimited by a first edge 14 and a second edge 15. With reference to the depressions 2 which are produced transversely with respect to the direction of advance 39 in the band-shaped support material 1, the intersection of edges 14, 15 defines a puncturing point 16. This expediently lies in the embossed depression 2, which can be configured as a groove or notch, for example. The puncturing point 16 can further be ground so that it is able to pierce human skin in order to collect a volume of blood. According to the view in Figure 3, the separating lines 5, along which the individual puncturing/measuring disposable bodies 6 are later separated from the band-shaped support material 1, are provided in a division 12. The division 12 and the spacing of the depressions 2, seen in the direction of advance 39 of the band-shaped support material 1, is dependent on the later width of the individual puncturing/measuring disposable bodies 6 to be produced and can be chosen freely. After the production, shown in Figure 3, of recesses 11 on the first face 9 of the band-shaped support material 1, a further processing of the band-shaped support material 1 takes place.

Please replace the paragraph beginning on line 12, page 8 with the following:

It can be seen from the view according to Figure 4 that the band-shaped support material 1, which is transported in direction of advance 39, is surrounded, in the area of the first face 9, by a soft plastic cover 18, for example of silicone material or any other suitable material. The soft plastic cover 18 can have a U-shaped profile so that the puncturing tips 16 ground and sharpened at the first face 9 of the band-shaped support material 1 are protected from damage in the area of the depressions 2. Moreover, the silicone material cover 18 provides for a permanent sterility of the points 16 at the first face 9 of the band-shaped support

material 1. The sterility is produced by irradiation with β or γ radiation or by heat and is maintained by surrounding the band-shaped support material with the soft plastic cover (silicone material cover) 18.

Please replace the paragraph beginning on line 22, page 8 with the following:

At the second face 10 of the band-shaped support material 1 lying opposite the soft plastic cover 18, a plastic cover 19 is likewise applied. ~~This can~~ Plastic cover 19 may be made of ~~any suitable plastic material other than silicone material~~ and serves for easier handling of the band-shaped support material 1. Accordingly, harder materials are preferably used. The plastic cover 19 can be used as a grip area 20. The plan view according to Figure 4 shows the areas of the depressions 2 which extend between the soft plastic cover 18 at the first face 9 and the plastic cover 19 at the second face 10 of the band-shaped support material 1. The separating line 5, along which individual puncturing/measuring disposable bodies 6 are separated from the band-shaped support material 1, is flush with the tip of the recesses 11 which were produced at the first face 9 of the band-shaped support material 1, which define the puncturing points 16 on both sides of the depressions 2 (see view according to Figure 3).

Please replace the paragraph on line 34, page 8 through line 16, page 9 with the following:

It will be seen from Figure 5 that the depressions of the band-shaped support material are provided with a cover and a detection element. In the view according to Figure 5, the band-shaped support material 1 is provided at the first face 9 with the soft plastic cover 18 for protecting against damage. The plastic cover 19 is arranged lying opposite this at the second face 10 of the band-shaped support material 1. A cover film 21 is applied between the soft plastic cover 18 and the plastic cover 19. At the same time, or separately from this, a detection element 22 narrower than the cover film 21 is applied to the band-shaped support material 1. The detection element 22 is configured in the manner described in German patent application DE 196 29 656 A1, the disclosure of which is expressly incorporated by reference herein, for example, and can be used for the detection of glucose in human blood. The detection element 22 is applied to the band-shaped support material 1 only after the latter has been sterilized by β or γ irradiation. Applying the detection element 22 afterwards has the advantage that the radiation-sensitive detection element 22 is not exposed to the sterilizing β or γ radiation, since such irradiation could greatly impair the functioning or efficacy of the detection element 22. According to the production method proposed according to the invention, the process steps of sterilization and of application of

a radiation-sensitive detection element 22 are distinct from one another, so that the detection element 22 is not impaired by the process step of sterilization by β or γ radiation.

Please replace the paragraph on line 25, page 9 through line 4, page 10 with the following:

The view according to Figure 6 shows an individual puncturing/measuring disposable body 6 with covered puncturing point 16 ~~and with a grip area.~~ In the production method proposed according to the invention for combined measuring and puncturing devices for detection of an analyte in liquid, the individual puncturing/ measuring disposable bodies 6 are separated from the band-shaped support material 1 along the separating lines 5 shown in Figures 2, 3 and 4. These bodies comprise, on both sides of the depression 2, which serves as capillary channel 23, a first lancet part 7 and a second lancet part 8. The separation of the individual puncturing/measuring disposable bodies 6 from the band-shaped support material 1 transported in the direction of advance 39 forms a first separating site 24 on the first lancet part 7 and a second separating site 25 on the second lancet part 8. The depression 2 suitable for capillary liquid transport lies underneath the cover film 21 and underneath the detection element 22. In the lower area of the individual puncturing/measuring disposable body 6, the latter is provided with a portion of the plastic cover 19, which can function as a grip area 20. The first face 9 of the individual puncturing/measuring disposable body 6 shown here is covered by the ~~silicone material~~ soft plastic cover 18.

Please replace the paragraph on line 6, page 10 through line 24, page 10 with the following:

Figure 7 shows an individual puncturing/measuring disposable body 6 with ~~the silicone material cover portion~~ soft plastic cover 18 removed. The depression 2, which can be formed like a groove or notch in the band-shaped support material 1, ends directly at the puncturing point 16. The puncturing point 16 can have a ground front part similar to an injection needle. A capillary channel mouth 27 of the depression 2 opens out in the puncture point 16. The depression 2, which serves as capillary channel 23 for capillary liquid transport, is formed with a capillary channel length 38. The width of the depression is indicated by reference number 37 and depends on the configuration of the punching or embossing tool with which the depressions 2 are produced in the band-shaped support material 1. The individual puncturing/measuring disposable body 6 comprises a first lancet part 7 and a second lancet part 8, at whose lines of separation 5 from the band-shaped support material 1 a separating side is in each case formed, designated by reference number

24 or 25. The depression 2, which forms the channel 23 suitable for capillary liquid transport, extends continuously from the capillary channel mouth 27 on the first face 9 of the individual puncturing/measuring disposable body 6 to the second face 10 of the band-shaped support material 1, here covered by the plastic cover ~~portion~~ 19.

Please replace the paragraph on line 29, page 10 through line 36, page 10 with the following:

Figure 8 shows a cross section, according to the cross section line VIII-VIII in Figure 7, through a capillary channel designed with a rounded depression base and suitable for liquid transport. The band-shaped support material 1 is covered by the detection element 22 in the cross-sectional plane. The detection element 22 has a thickness 28; ~~the~~ The thickness of the band-shaped support material 1, preferably configured as a thin metal film with a thickness of 0.1 to 0.3 mm, is indicated by reference number 30.

Please replace the paragraph beginning on line 2, page 11 with the following:

In the view according to Figure 8, the base 4 of the depression 2 is designed with a rounded shape 34. A supply of liquid, for example human blood, is taken up by the capillary channel 23 extending perpendicular to the plane of the drawing in Figure 8 and suitable for capillary liquid transport. This channel merges into the detection element 22 and forms, in the latter, a saturated zone 33. The supply of liquid 32 that can be taken up in the depression 2 and the capillary channel 23 depends on the depth of the depression 2, i.e. on the depth of embossing into the band-shaped support material 1. With a capillary channel length 38 of approximately 15 mm and a capillary channel width 37 of approximately 0.25 mm, ca. 100 nl of human blood can be taken up in the capillary channel, on condition that the base 4 of the depression 2 has a rounded shape 34. The time needed for a sufficient volume of liquid to pass into the depression 2 functioning as capillary channel 23 and located underneath the cover film 21 and the detection element 22 depends on the configuration of that surface of the band-shaped support material 1 forming the capillary base and on the materials used for cover film 21 and detection element 22. If aluminium, for example, is chosen, its oxidized surface can be made highly hydrophilic.

Please replace the paragraph on line 18, page 11 through line 26, page 11 with the following:

Figure 9 shows the formation of a depression of triangular cross section in the band-shaped support material. In this embodiment ~~variant too~~, the band-shaped support material 1 is covered on its top face by a detection element 22. A supply of liquid 32, for example human blood, passes into the depression 2 designed with a triangular shape 35 and forms a saturated area 33 in the detection element 22. According to the view in Figure 9 ~~too~~, the material thickness of the detection element is identified by reference number 28, while the material thickness of the band-shaped support material 1 is identified by reference number 30.

Please replace the paragraph beginning on line 31, page 12 with the following:

The removal of the soft plastic ~~material~~ cover 18, which ~~[[can]]~~may be made of silicone material or of a hydrophilic plastic, ~~[[can]]~~may also be automated using a measurement system, for example if the measurement system comprises an apparatus with a magazine for receiving the combined puncturing and measuring devices proposed according to the invention for detection of an analyte in liquid. As regards the wetting of the combined puncturing and measuring device, it should be noted that the wetting of the combined puncturing and measuring device takes place in a separate step following the production of a skin incision, by guiding the puncturing point 16 to a drop of blood formed on the skin surface. The puncturing point 16 of the combined puncturing and measuring device can also be guided repeatedly to the drop of blood and inserted repeatedly into the skin incision, in order to achieve contact between the emerging body fluid, for example blood, and the depression 2, 23 forming a capillary channel or the detection element 22 or the combined puncturing and measuring device.

Please insert after the last paragraph ending on line 14, page 13 the following new paragraph:

Although the invention has been described in detail with reference to illustrated embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

Please delete the heading and List of reference numbers on line 1, page 14 through line 6, page 15.